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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	10/564,932
Filing Date	January 13, 2006
First Named Inventor	Frank THEOBALD
Art Unit	1614
Examiner Name	Unknown
Attorney Docket Number	03/058 LTSBOE

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Remarks

English translation of the International Preliminary Report on Patentablility

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ProPat, LLC		
Signature	Cathy Moore		
Printed name	Cathy R. Moore		
Date	July 17, 2006	Reg. No.	45,764

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	Claire Wygand		
Typed or printed name	Claire Wygand	Date	July 17, 2006

PATENT COOPERATION TREATY

PCT/EP2004/007770

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

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28. Juni 2006
ZK PT SW AZ

Date of mailing *(day/month/year)* 22 June 2006 (22.06.2006)	
Applicant's or agent's file reference 03/058 LTSBOE	**IMPORTANT NOTIFICATION**
International application No. PCT/EP2004/007770	International filing date *(day/month/year)* 14 July 2004 (14.07.2004)
Applicant LTS LOHMANN THERAPIE-SYSTEME AG et al	

1. **Transmittal of the translation to the applicant.**

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

KR

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yolaine Cussac
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 70 80

Form PCT/IB/338 (January 2004)

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
03/058 LTSBOE		
International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/EP2004/007770	14.07.2004	23.07.2003

International Patent Classification (IPC) or national classification and IPC

A61K31/428, A61K9/70

Applicant

LTS LOHMANN THERAPIE-SYSTEME AG

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☒ (*sent to the applicant and to the International Bureau*) a total of 2 sheets, as follows:

      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s))

      _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/007770

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages 1-10 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-30 received by this Authority on 23.05.2005 with letter of 23.05.2005

nos.* _____ received by this Authority on _____

☐ the drawings:

sheets _____ as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/007770

Box No. III **Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 19-22, 27-30

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 19-22, 27-30

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/007770

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	16, 21	YES
	Claims	1-15, 17-20, 22-30	NO
Inventive step (IS)	Claims		YES
	Claims	1-30	NO
Industrial applicability (IA)	Claims	1-18, 23-26	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

See Supplemental Box.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Continuation of Boxes III and V

BOX III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claims 19 to 22 and 27 to 30 relate to subject matter which, in the opinion of this Authority, falls under **PCT Rule 67.1(iv)**. Consequently no expert opinion has been established regarding the industrial applicability of the subject matter of these claims (**PCT Article 34(4)(a)(i)**).

BOX V

Reasoned statement with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

This report refers to the following documents:

D1: EP 0 428 038 A (BOEHRINGER INGELHEIM), 22 Mai 1991 (1991-05-22)

D2: WO 03/015779 A (HEXAL), 27 February 2003 (2003-02-27)

D3: WO 02/03969 A (HEXAL), 17 January 2002 (2002-01-17)

D4: WO 00/74661 A (NOVEN PHARMACEUTICALS), 14 December 2000 (2000-12-14)

D5: WO 03/011291 A (HEXAL), 13 February 2003 (2003-02-13)

D6: WO 96/18395 A (UPJOHN), 20 June 1996 (1996-06-20)

Supplemental Box

1. The PCT Contracting States do not have uniform criteria against which the industrial applicability of **claims 19 to 22 and 27 to 30** in the present application can be assessed. Patentability may depend on the wording of the claims. For example, the European Patent Office does not recognise the industrial applicability of claims to the medical use of a compound. It may, however, allow claims to the first medical use of a known compound or to the use of such a compound in the preparation of a drug for a new medical application.

2. The application fails to meet the requirements of **PCT Article 33(1)** because the subject matter of **claims 1, 3, 4, 7 to 15, 19, 20, 22 to 24, 26 to 28 and 30** is not novel (**PCT Article 33(2)**) over document D1.

Document D1 describes a transdermal therapeutic system for treating **schizophrenia** and **parkinsonism**, consisting of a back layer, a peel-off protective film and **an active-principle-containing film reservoir**, exactly as in the present invention, **the active principle (Pramipexol or its (-) enantiomer) being contained in an emulsion polymerised polyacrylate polymer layer.** The polyacrylate polymer layer is of the type Eudragit NE 30 D (R) **(a mixture of carboxyl-group-free polymerised acrylic esters and methacrylic esters). The system can apply between 0.5 and 5 mg of the active principle per day with a flow rate of more than 10 micrograms/cm^2 h** *(see D1, page 2, lines 40 to 50; also the claims, example 1 and figure I).*

The subject matter of **claims 1 to 9, 14, 19, 22, 23,**

25 to 27, 29 and 30 lacks novelty (**PCT Article 33(1) and 33(2)**) over document **D2**.

Document D2 discloses (the references in parentheses are to D2) a transdermal therapeutic system for treating **parkinsonism**, consisting of a cover layer, a peel-off protective film and one (or more) **active-principle-containing matrix layer(s), the active principle (Pramipexol or salts or solvates thereof) being contained in an polyacrylate polymer layer**. The polyacrylate polymer layer can be of the type Durotak 2287 (R), exactly as in the present invention (*see D2, page 4, third paragraph to page 8, first paragraph; also the claims and examples*).

In a similar way the subject matter of **claims 1 to 9, 14, 17 to 19, 23 and 27** lacks novelty (**PCT Article 33(1) and 33(2)**) over document **D3**.

Document D3 discloses (the references in parentheses are to D3) a transdermal therapeutic system comprising a cover layer, a peel-off protective film and **one (or more) active-principle-containing self-adhesive matrix layer(s)**, in which **the active principle, which can be an antiparkinsonism agent such as Pramipexol, is contained in an polyacrylate polymer layer**. The polyacrylate polymer layer can be of the type **Durotak (R)**, exactly as in the present invention (*see D3, page 13, third paragraph; page 8, first paragraph to page 9, first paragraph; and the claims*). **The system can contain penetration promoters (such as silicon dioxide or alcohols such as 1,2-propane diol) or stabilisers.**

In a similar way the subject matter of **claims 1 to 9, 14, 17 to 19, 23 and 27** lacks novelty (**PCT Article 33(1) and 33(2)**) over document **D4**.

Document D4 discloses (the references in parentheses are to D4) a transdermal therapeutic system comprising **an active-principle-containing self-adhesive matrix layer**, in which **the active principle, which can be an antiparkinsonism agent such as Pramipexol, is contained in an polyacrylate polymer layer**. The polyacrylate polymer layer, which can be of the type **Durotak (R)**, exactly as in the present invention, contains a polymerised hydroxyl-group-containing acrylic ester (*see D4, page 18, first paragraph; and the claims and examples*). **The system can contain penetration promoters (such as alcohols or diols such as 1,2-propane diol) or stabilisers (such as esterified cellulose derivatives).** The subject matter of **claims 1 to 15, 17 to 20 and 22 to 30** therefore lacks novelty (**PCT Article 33(1) and 33(2)**).

3. **The application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1 to 30 does not involve an inventive step (PCT Article 33(3)).**

Regarding the subject matter of **claims 1 to 30**, documents **D1 to D4** appear to be of particular relevance in connection with the question of inventive step. They in fact solve **the same problem**, namely that of providing transdermal therapeutic systems comprising a back layer

Supplemental Box

and an active-principle-containing polymer matrix, and containing **an antiparkinsonism agent such as Pramipexol (or its (-) enantiomer or salts or solvates thereof)**. The active-principle-containing polymer matrix is **a polyacrylate polymer layer** created from **a mixture of carboxyl-group-free and hydroxyl-group-containing polymerised acrylic esters and methacrylic esters**. These transdermal therapeutic systems are designed to have a particular daily release rate and flow rate.

Regarding the subject matter of **claims 16 and 21**, it seems to be normal to choose a specific concentration of the active principle and to use Pramipexol as a neuroprotective drug (the neuroprotective action of Pramipexol is well established; see document D6).

The present application therefore does not appear to meet the requirements of **PCT Article 33(1)** and **33(3)** with respect to the aforementioned documents in so far as novelty is concerned.